DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Streamlining the Blood Donor History Questionnaire; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Streamlining the Blood Donor History Questionnaire.'' The purpose of the public workshop is to streamline the blood donor history questionnaire without compromising the safety of the nation's blood supply. The public workshop is jointly sponsored by FDA and the American Association of Blood Banks.

Date and Time: The public workshop will be held on October 16, 2000, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Lister Hill Conference Center, National Institutes of Health, Building 38A, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (address above) by Friday, October 6, 2000. There is no registration fee for the public workshop. Seating is limited, therefore interested parties are encouraged to register early. Registration at the site will be done on a space available basis on the day of the public workshop, beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

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Agenda: The public workshop is expected to address, but is not limited to, the following issues and topics: (1) The role of the blood donor interview in assuring blood safety; (2) overview of past efforts to improve the donor history questionnaire; (3) different methodologies in performing donor history evaluations; (4) validating the donor history questionnaire as a tool for reducing and eliminating risks to the blood supply; (5) analysis of error and accident reports and post donation information that resulted from inaccurate or misleading donor history responses; and (6) suggestions on how the donor questionnaire can be streamlined without compromising either donor, product, or recipient safety.

The public workshop agenda will be posted on the FDA Internet as soon as the information becomes available. The FDA Internet address is http://www.fda.gov/cber/whatsnew.htm.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–

16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on the FDA Internet site at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 9/14/00
September 14, 2000

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